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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,422	04/16/2007	Robert Hes	0218.094.0002	3688
68153 7590 08/04/2010 GLOBUS MEDICAL, INC. ATTN: BRIAN MALM VALLEY FORGE BUSINESS CENTER 2560 GENERAL ARMISTEAD AVENUE AUDUBON, PA 19403				
EXAMINER LAWSON, MATTHEW JAMES				
ART UNIT		PAPER NUMBER		
3775				
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08/04/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,422

**Applicant(s)**

HES ET AL.

**Examiner**

MATTHEW LAWSON

**Art Unit**

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 15 has been renumbered claim 17 and claims 15-16 which were previously non-elected are canceled.

Claims 1-14 are objected to because of the following informalities: Claim 1 recites in line 2 "*(having a thread lead)*" by having the parentheses around this limitation is unclear if this limitation is solely implied or being positively claimed. The applicant is advised to either delete the limitation if it is implied, for it would be inherent or to delete only the parentheses to positively claim this limitation. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7, 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "the thread on each end of the lead and tail portions having an approximately constant diameter along a significant portion of its length," and the claim also recites "the thread on the tail portion is greater than that of the thread on the lead portion", which is the narrower statement of the range/limitation.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant claims that the value of the thread aspect ratio is defined by an expression but does not positively recite this expression making the expression

indefinite.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 14 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 14, lines 1-2, applicant positively recites part of a human, i.e. "has a bone extending through it along its length." Thus claim 14 includes a human within their scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Vrespa (US 5,593,410).

Vrespa discloses a bone screw (figure 1) having a lead portion (24, figure 8) and a tail portion (23, figure 8), and an intermediate transition portion (22, figure 8), each of the lead portion and the tail portion comprising a root (32-24, figure 1) and a thread (26/28, figure 1), having a thread lead (figure 1) formed on the root, the thread on the lead portion having an approximately constant diameter along a significant portion of its length and tail portion having an approximately constant diameter along a significant portion of its length (figure 1), in which the diameter of the thread on the tail portion is greater than that of the thread on the lead portion (figure 1), and in which the thread lead of the thread on the lead portion is equal to the thread lead of the thread on the tail portion (figure 1), wherein the intermediate transition portion is configured between the threads of the lead portion and the tail portion, and is provided with a diameter that decreases gradually between the thread of the lead portion and the thread of the tail portion (figure 8), wherein the tail portion is provided with a socket end (16, figure 1), wherein the socket end of the tail portion is adapted to be, *i.e. capable*, flush with the surface of the bone or under the surface of the bone after the bone screw is fully inserted, and the thread on the lead portion of the screw is a multi-start thread (column 12, lines 55-58) in which the number of starts of the thread on the lead portion is equal to the ratio of the thread pitch of the thread on the tail portion to the thread pitch of the thread on the lead portion (column 12, lines 63-67), and the thread on the tail portion of the screw is a single-start thread (column 12, line 43), in which the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion (figure 1), and the diameter of the root of the tail portion is greater than the diameter of the root of

the lead portion, and has a bore (30, figure 1, and 74, figure 4-5) extending through it along its length.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6-7, 9-10, 12-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410).

Regarding claim 4, Vrespa discloses the lead portion being a triple start thread instead of the double start thread and the thread pitch of the tail portion being equal to three times the thread pitch of the thread on the lead portion (column 12, lines 63-67). It would have been obvious to one of ordinary skill in the art to reduce the start threads from three to two and the pitch height to two times as large.

Regarding claims 6-7, Vrespa discloses the claimed invention except for the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion is at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion to be at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an

optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 9-10, Vrespa discloses the claimed invention except for the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion is at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion to be at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12-13, Vrespa discloses the claimed invention except for the ratio of the diameter of the thread aspect on the tail portion to that of the thread aspect ratio on the lead portion is at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread aspect ratio of the tail portion with respect to the lead portion to be at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).



Regarding claim 17, Vrespa discloses the claimed invention except for the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Frigg et al. (US 5,180,382).

Vrespa discloses the claimed invention except for the threading on the tail portion of the screw being a continuation of the one of the threads on the lead portion.

Frigg et al. discloses the threading on the leading portion (7, figure 1) with threading and a tail portion (6, figure 1) with threading which is a continuation of the threading on the lead portion (figure 1) to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body. Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the device of Vrespa to having continuous threading between the leading and trailing portions of the screw to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body as taught by Frigg et al.

### ***Response to Arguments***

Applicant's arguments filed June 4<sup>th</sup>, 2010 have been fully considered but they are not persuasive. The applicant argues that Vrespa fails to teach or suggest *"the tail portion being provided with a socket end, wherein the socket end of the tail portion is adapted to be flush with the surface of the bone or under the bone surface after the bone screw is fully inserted."* The examiner respectfully disagrees, the device of Vrespa indeed teaches a socket end (16, figure 1) and although Vrespa does teach that the cylindrical neck of the device is intended to be implanted with the top most portion of the neck extending out from the bone the device is adapted to or capable of being inserted flush with or beneath the bone surface. Accordingly, Vrespa does indeed anticipate this limitation.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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